THE COMMITTEE ON ENERGY AND COMMERCE

INTERNAL MEMORANDUM

April 8, 2011

MEMORANDUM

To: Members, Subcommittee on Oversight and Investigations

From: Oversight and Investigations Staff

Subject: April 13, 2011, Hearing on "Import Safety: Status of FDA's Screening Efforts at the Border"

On April 13, 2011, at 10:30 a.m., in Room 2123 Rayburn House Office Building, the Subcommittee on Oversight and Investigations will hold an oversight hearing entitled "Import Safety: Status of FDA's Screening Efforts at the Border." This hearing will examine the current state of Food and Drug Administration (FDA) import screening processes and the pace of the agency's nationwide rollout of the promising risk-based automated entry review system known as PREDICT.

I. Witnesses

The hearing will have one witness: The Honorable Margaret A. Hamburg, M.D., Commissioner of the Food and Drug Administration.

II. Discussion

Whether it is melamine-tainted food, adulterated heparin or counterfeit pharmaceuticals, there are potentially fatal consequences from inadequate oversight of the global food and drug supply chain. For instance, last month, Commissioner Hamburg estimated that over 80 Americans had died from contaminated batches of imported heparin from China in 2008.

Approximately 24 million import entry lines of food, drugs, cosmetics, and medical devices are expected to arrive at U.S. ports of entry this year. According to FDA data, FDA-regulated products are currently imported by more than 130,000 importers of record, who ship from over 300,000 foreign facilities in more than 150 countries. It is estimated that 15 to 20 percent of our food supply originates outside of the United States and up to 40 percent of the drug products and 80 percent of active pharmaceutical ingredients come from foreign sources.

The sheer volume of imports precludes the FDA from inspecting more than two percent of the products under its jurisdiction before they enter into U.S. commerce. With this in mind, the FDA has been discussing the development and implementation of a risk-based automated import examination system for many years. The proof-of-concept for a software system known as PREDICT—the Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting—was submitted to the FDA in 2005. To date, PREDICT has been deployed in four FDA districts out of twenty—Los Angeles, New York, San Francisco, and Seattle. When fully operational, PREDICT will use FDA-developed criteria to strategically inspect shipments of products posing the greatest risk, while allowing low-risk shipments to enter U.S. commerce in an expedited fashion.

PREDICT will replace the outdated electronic screening function of OASIS—the Operational and Administrative System for Import Support—that has numerous documented vulnerabilities. PREDICT generates a numerical score for all FDA-regulated imports based on certain relevant criteria, including the product's historical data, importer, manufacturer, and country of origin; results of laboratory analyses and foreign facility inspections; and general intelligence on recent events such as natural disasters and foreign recalls. PREDICT estimates the risk intrinsic to each and every shipment and notifies the entry reviewer if the score that is returned by the system is above an FDA-specified threshold and should be targeted for examination. Shipments that are below the threshold receive a "may proceed" message, unless other conditions are present that require their further examination or detention.

From June through September 2007, FDA conducted a pilot test of PREDICT by screening shipments of seafood products at several ports in Los Angeles. In contrast to OASIS, (1) PREDICT improved the agency's ability to identify imports which were more likely to violate FDA regulations; (2) the violations, on average, posed a greater risk to human health; and (3) PREDICT allowed a greater percentage of shipments the agency considers to be low risk to enter U.S. commerce without requiring manual review.

FDA initially planned to deploy PREDICT on a district-by-district basis for all FDA-regulated products beginning in April 2009. This date was then pushed back to September 2009 because of delays in developing a system interface between PREDICT and OASIS. On February 4, 2010, Commissioner Hamburg announced that "hopefully [FDA] will have it up and running across the country by the end of the spring." On April 12, 2010, FDA informed the General Accountability Office (GAO) that PREDICT was fully operational in the Los Angeles and New York districts but that the scheduled nationwide rollout in the summer of 2010 had been delayed primarily because of technical problems such as server crashes and overloads. According to an October 2010 report in *FDA Week*, an FDA official cited changes to the network and field computers that would enable deployment to additional ports with the goal of implementing the system in all districts by the end of the year. To date, the only additional districts to which PREDICT has been deployed are Seattle and San Francisco. At a recent bipartisan staff briefing, FDA officials said that further rollout had again been delayed due to technical issues but that they believe the problems have been resolved and deployment to the remaining districts can proceed.

III. Issues

The following issues will be examined at the hearing:

- The globalization of the supply chain and the FDA's efforts to maintain effective screening controls for imported items.
- What are FDA's proposed solutions for enhancing the screening of the growing number of imports of food, drugs and medical devices?
- Does FDA expect deployment of PREDICT at all FDA districts by the end of the year?
- What has FDA done in the meantime to enhance risk-based import screening at ports of entry and/or address vulnerabilities in OASIS?
- What is FDA doing to improve its IT infrastructure for import screening?

IV. Staff Contacts

If you have any questions regarding this hearing, please contact Sam Spector (samuel.spector@mail.house.gov) or John Stone (john.stone2@mail.house.gov) of the Oversight and Investigations staff at (202) 225-2927.